SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK
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EVA DAVID,

INDEX NO. 805218/2016

Plaintiff,

- against -

JULIAN A. DECTER, M.D.,

Defendant.
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JOAN A. MADDEN, J.:

In this action seeking damages for alleged medical malpractice and lack of informed consent, plaintiff Eva David ("Ms. David" or "plaintiff") moves for summary judgment as to liability on her claim for medical malpractice. Defendant Julian Decter, M.D. ("Dr. Decter" or "defendant") opposes the motion.

Background

This action arises out of Dr. Decter's treatment of plaintiff Non-Hodgkin's Lymphoma ("NHL"),with an antibody drug called Rituxan With respect to the medical malpractice claim, the Bill of Particulars alleges that Dr. Decter deviated from the accepted medical practice in negligently failing (I) to take a blood test to determine if plaintiff had Hepatitis B prior and during her treatment with Rituxan, to determine if plaintiff had Hepatitis B, and (ii) to treat plaintiff with a drug along with Rituxan to counteract the effect of Rituxan and to prevent Hepatitis B reactivation. It is alleged that as a result of the Dr. Decter's malpractice, plaintiff suffers from uncontrollable Hepatitis and has permanent damage to her liver and is at increased risk for liver cancer.

The following facts are based on Dr. Decter's deposition testimony, plaintiff's deposition testimony, and the medical records related to plaintiff's diagnosis and treatment for the NHL and Hepatitis B.

Plaintiff first saw Dr. Decter on June 9, 2014 to confirm a diagnosis of NHL, which is a form of blood cancer affecting white blood cells (lymphocytes) which are part of the immune system. After confirming that NHL diagnosis, Dr. Decter decided to treat plaintiff with six rounds of "R-Chop" chemotherapy, which is a treatment with four different drugs, one of which is Rituxan. On June 16, 2014, Dr. Decter gave plaintiff her first round of R-Chop. Approximately every three months, Dr. Decter would administer another round of R-Chop and take blood tests, but he never tested plaintiff for Hepatitis B.

At his deposition, Dr. Decter stated that he never tested for Hepatitis B because plaintiff did not have any of the risk factors that patients with Hepatitis B have. Specifically, defendant testified he screened plaintiff for Hepatitis through her history, physical and lab studies and even though the screening did not rule out the possibility of having Hepatitis B, the results rendered plaintiff at the lowest possible risk of having Hepatitis B. (Defendant EBT, at 59-60, 62-63). Dr. Decter also testified that he was aware when he treated plaintiff in June of 2014 that some patients could be occult carriers of Hepatitis B, meaning their immune system suppresses the Hepatitis B so that it only emerges when the immune system is suppressed. (Id., at 78). However, according to defendant, he nonetheless chose not to test plaintiff for Hepatitis because "[i]t was [his] judgement she was at the lowest possible risk for being a carrier of [Hepatitis B]." (Id., at 62). He also testified that "the professional societies, either the ASH (i.e. The American Society of Hematology) or ASCO (i.e. The American Society of Clinical Oncology), do not

recommend screening all patients, only selected patient [at] high risk. And it was those recommendations that I followed." (Id., at 60-61).

Dr. Decter testified that plaintiff's ALT and AST levels, which relate to liver activity, were first abnormal on November 3, 2014,[1] and on that date plaintiff's skin was yellowish, which was consistent with jaundice (Id., at 42, 55, 99). On the next visit, December 16, 2014, Dr. Decter's notes state that plaintiff's "abnormal liver function studies [were] likely due to medication or hepatitis." (Id., at 100). His notes later state that there were no symptoms of Hepatitis B. Dr. Decter tested for Hepatitis after that visit, but only for Hepatitis C. When asked why, Dr. Decter testified that Hepatitis C was much more likely than B considering plaintiff's background and history. On December 16, 2014, after six rounds of chemotherapy and plaintiff reported having a tender abdomen, Dr. Decter tested plaintiff for Hepatitis B, and she tested positive (Id., at 54-56).

On December 22, 2014, plaintiff's private physician, Sam Moskowitz, M.D., confirmed the blood test results indicating that plaintiff had Hepatitis B and plaintiff was admitted to New York Presbyterian, Weill Cornell Medical Center to treat her Hepatitis B (Id., at 109). Dr. Decter last saw plaintiff in his office on June 1, 2015.

On May 26, 2016, plaintiff commenced this action asserting claims for medical malpractice and lack of informed consent. After defendant answered the complaint, and plaintiff served her Bill of Particulars, defendant moved to strike all reckless language and claims of punitive damages in plaintiff's Bill of Particulars and to preclude plaintiff from introducing testimony at trial covering any allegations of recklessness or claims of punitive

[1] However, the record shows that on July 11, 2014, a blood test showed that ALT levels were abnormal, albeit less severely than November's readings (Exhibit 3).

damages. Plaintiff opposed the motion, which the court denied by decision and order dated November 9, 2017.

After discovery was completed, plaintiff made this motion for summary judgment as to liability on her medical malpractice claim, asserting that the evidence establishes that defendant departed from accepted practice in failing to test plaintiff for Hepatitis B before and during her treatment for NHL with Rituxan.

In support of her summary judgement motion, plaintiff submits the expert affidavit of Robert Soiffer, a physician licensed to practice in the state of Massachusetts, who is a hematologist oncologist. He states that he has been consulted by/or treated 600 patients with NHL, and that he is "fully familiar with the standards of care for the treatment of [NHL], including the use of the medication Rituxan" (Soiffer Aff ¶ 6). Dr. Soiffer states that in June 2014, when plaintiff was being treated by Dr. Decter, and for several years before that "it was the standard of care that NHL patients for whom Rituxan was intended for treatment to undergo blood tests to rule out prior exposure to the Hepatitis B virus." (Id ¶ 17). In addition, he states that "[i]n 2014, the standard of care by hematologist-oncologists who treat patients for NHL and utilize R-CHOP chemotherapy required both testing patients for Hepatitis B before treatment begins and monitoring the patient for several months after treatment is concluded because the virus can be activated after treatment is completed. The monitoring consists of blood tests and examination for clinical signs and symptoms for Hepatitis B, including tiredness or jaundice." He also states that "[p]re-treatment testing for Hepatitis B is essential because exposure to Hepatitis B can occur without the patient ever being aware of the fact. A patient can even have active Hepatitis B without ever being aware that they are sick."

In connection with the instant action, after reviewing the records and the litigation materials related to the plaintiff's treatment by Dr. Decter, and Dr. Decter's deposition, Dr. Soiffer opines that "Dr. Decter did not meet the standard of care required of a Board-Certified Hematologist Oncologist providing treatment to a NHL patient" (Id, ¶ 's 24, 25). Dr. Soiffer states that there is "a plethora of literature" prior to June 2014 dedicated to documenting the phenomenon of Rituxan reactivating Hepatitis B in patients and that in September 2013, after a full review and proceeding, the FDA "added a 'Black Box' warning to the required prescribing information for Rituxan used for treatment of [NHL]," and that people who had no known exposure to Hepatitis B were found to have it via Rituxan (Id., ¶s 22, 26). He states that "the FDA directed that all patients irrespective of 'risk factors' be screened for Hepatitis B prior to the commencement of NHL treatment with Rituxan."

Dr. Soiffer notes that Dr. Decter admitted at his deposition that before his treatment of plaintiff, he was "aware of the danger of [Hepatitis B] activation and/or reactivation during Rituxan treatment of NHL" but was unaware of the "black box" warning from the FDA that all patients undergo Hepatitis B screening by blood test prior to undergoing treatment with Rituxan (Id., ¶ 27, 28, citing Dr. Decter's EBT at 34-35).

As for defendant's reliance on the American Society of Clinical Oncologists ("ASCO") guidelines that were in place as of 2014, Dr. Soiffer states that these guidelines suggest that patients treated with Rituxan should be first tested for Hepatitis B. Specifically, he points to that part of the guideline that states that "[p]hysicians may consider screening patients belonging to groups at heightened risk for chronic [Hepatitis B] infection or if highly immunosuppressive therapy is planned...[which] include...regimens including rituximab.[2]" Dr. Soiffer opines that

[2]Rituxan is the brand name of rituximab.

"Dr. Decter failed to follow the standard he claims he should have," including failing to test for Hepatitis B while treating plaintiff, even though he did order multiple blood tests and base line level function tests (ALT and AST)" (Id, ¶s 29, 32, 33). Dr. Soiffer states that plaintiff's pre-treatment ALT and AST levels "were well within normal limits;" however, by July 2014, plaintiff's "liver function tests began showing abnormal results [but][d]espite these changes Dr. Decter continued the chemotherapy [without] testing Ms. David for Hepatitis B." (Id., ¶s 33, 35). Dr. Soiffer also notes that on November 3, 2014, when Dr. Decter noticed plaintiff was jaundice, he ordered a Hepatitis C blood test, but not a Hepatitis B blood test, despite "ongoing liver injury... [and] failed to consider that Ms. David was at risk [for Hepatitis B] (Id., ¶ 36, 37). Dr. Soiffer opines that this "failure . . . allowed the Hepatitis B virus to continue to replicate unchecked." (Id.)

Dr. Soiffer opines that Ms. David's liver damage "was likely avoidable had Dr. Decter simply followed the generally accepted standard of care." (Id., ¶ 42). Dr. Soiffer opines that "Dr. Decter departed from accepted practice by failing to test Ms. David for Hepatitis B," and that at this time occult carriers[3] of the virus were known to exist, and clinicians were to be aware of them when treating patients for NHL (Id., ¶ 45). Dr. Soiffer opines that "to protect patients from developing Hepatitis B reactivation related to [Rituxan], it is standard practice now and was in 2014 to perform required blood tests before instituting treatment with [Rituxan] for NHL" which "Dr. Decter failed to do. . . despite acknowledging that patients he sees for NHL treatment can be occult carries of Hepatitis B" (Id., ¶ 46). Dr. Soiffer opines that it was inappropriate "for Dr. Decter to risk Ms. David's health and life on his speculation that her

[3] An occult carrier is defined as "a patient who has no clinical signs of Hepatitis B infection and has normal liver function tests yet carries [Hepatitis B] DNA in their blood or liver." (Id.).

lifestyle made it unlikely that she could have been exposed to [the] Hepatitis B virus, when a routine blood test would have ruled it in or out." (Id., ¶ 48).

Dr. Soiffer opines that Ms. David was at risk, because, among other reasons, "she was born prior to the advent of the vaccine which is now routinely given to children shortly after birth [and] Dr. Decter's statement that he did not believe her to be 'at risk' of exposure demonstrates a lack of understanding of that risk and a failure to stay current on trends in oncology treatment." (Id., ¶ 49, 50). "This was a serious departure from accepted practice because of it exposed Ms. David to activation of the Hepatitis B and has put her life in jeopardy despite apparently successful treatment for NHL." (Id.). Dr. Soiffer further opines that during treatment, when plaintiff's ALT and AST levels began to rise, "Dr. Decter's failure to immediately test Ms. David for Hepatitis B was a further departure from accepted practice that delayed appropriate treatment for Hepatitis B, thus placing her at further risk for severe liver damage." (Id., ¶ 51). Finally, Dr. Soiffer opines that "another red flag that was ignored" was plaintiff's skin turning yellow, however, Dr. Decter decided not to test Hepatitis B; in fact, he tested instead for Hepatitis C, which "has no logic." (Id., ¶ 52).

Plaintiff also submits the expert affirmation of Sam Moskowitz, M.D., a physician licensed to practice in the state of New York who is a board-certified gastroenterologist and who provided medical care to plaintiff after she developed the Hepatitis B infection. Dr. Moskowitz's opinion is consistent with that of Dr. Soiffer, including that plaintiff's treatment with Rituxan "re-activated her Hepatitis B virus" and that in 2014, when plaintiff was treated, it was "well-known" that such treatment could re-activate the virus (Moskowitz ¶ 9). He also opines that to prevent the re-activation of the virus "patients are supposed to be tested for Hepatitis B exposure prior to treatment" (Id., ¶ 10). Dr. Moskowitz states that "[t]o determine if

a patient has been exposed or is a carrier of [Hepatitis B], even without risk factors, blood test can be done before treatment starts [and if Hepatitis B] exposure is found...then anti-viral drugs can be given to prevent reactivation of the [Hepatitis B] virus" (Id, ¶ 12).

Plaintiff also relies on her own affidavit in which she avers that "Dr. Decter never tested [her] blood for the presence of [Hepatitis B] before he started to treat [her] lymphoma." (Plaintiff Aff., ¶ 12). Plaintiff also states that "Dr. Decter never discussed that he knew about the activation of dormant [Hepatitis B] during Rituxan treatment for [NHL] or that 2 simple blood tests were all that was required prior to commencing cancer treatment to avoid activation of the [Hepatitis B]", nor did he tell her "that the FDA and other governmental and non-governmental professional organizations had expressly recommended testing all [NHL] patients for [Hepatitis B] prior to commencement of chemotherapy that included Rituxan." (Id., ¶ 13, 14). If defendant had informed her of this information, plaintiff states that she "would have agreed to have all the necessary blood tests and any anti-viral treatment needed to prevent what had happened" (Id.).

In opposition, defendant submits an expert affirmation of Alan Pollock, M.D., a physician licensed to practice medicine in New York State, who is Board-Certified in internal medicine with a sub-speciality in infectious disease (Defendant's Affirmation. ¶ 1). Dr. Pollack states that he is "familiar with the applicable standards of care in the treatment and diagnosis of ...[NHL] and Hepatitis B... and keep abreast of the relevant peer reviews and other medical literature regarding diagnosis and treatment of these conditions" (Id, ¶ 2).

Upon review of the relevant medical records, all relevant depositions, and the Bill of Particulars, Dr. Pollock opines that "within a reasonable degree of medical certainty. . . Dr. Decter committed no departures from the standard of care in his treatment of the plaintiff" (Id., ¶ 2). Dr. Pollock states that plaintiff "did not previously exhibit any of the signs or symptoms of

liver damage or [Hepatitis B] before consulting with Dr. Decter", nor did she have "any of the well-established risk factors of [Hepatitis B]" (Id., ¶ 3).

Dr. Pollock also opines that it is "not the strict standard of care for a treating physician to refer all patients undergoing treatment with Rituxan for [Hepatitis B] testing." (Id., ¶ 8). "It is uncontroverted that some of the relevant medical literature, including the 'black box' warning on Rituxan state that [Hepatitis B] is ***recommended*** for patients undergoing treatment with Rituxan." (Id.)(emphasis in the original). However, Dr. Pollock opines that testing is only ever a recommendation, not a requirement; "nowhere does it state that the testing is mandatory in all cases." (Id.). He further states that "[w]hile it is true that activation of latent [Hepatitis B] in patients with that condition is a known risk of treatment with Rituxan, it is my opinion, to a reasonable degree medical certainty, that it is a matter of physician's discretion based upon the clinical presentation of the patent and the totality of the circumstances whether pre-treatment screening of [Hepatitis B] should be performed [and that] "testing for [Hepatitis B] throughout the course of treatment with Rituxan is also a matter of physician discretion that is dependent upon the clinical presentation of the patient and the totality of circumstances." (Id, ¶ 9).

In addition, Dr. Pollack states that "plaintiff can offer no proof as to what her antibody status would have been had the testing been done" (Id., ¶ 8). Dr. Pollock opines that "[b]y her own admission, Ms. David's [Hepatitis B] infection was properly characterized as an 'occult' condition", and she presented none of the known risk factors for Hepatitis B, so "it was a reasonable exercise of clinical judgment by Dr. Decter not to screen Ms. David for [Hepatitis B] at the start of the treatment," as well as throughout treatment (Id., ¶'s 10, 11).

In reply, plaintiff points out that Dr. Pollack does not practice oncology nor does he claim he treats NHL or other cancer patients. Furthermore, plaintiffs argues that while Dr.

Pollack states that the FDA Black Box Warning and the ASCO guideline are "mere recommendations" not strict standards, he provides no foundation for his opinion. Plaintiff also contends that defendant's expert does not address the abnormal ALT or AST (liver enzyme) blood test results obtained in November 2014, and that plaintiff appeared or provide any explanation about way defendant tested for Hepatitis C after those blood tests, but not Hepatitis B.

Discussion

"To establish a prima facie case of liability in a medical malpractice action, [she] must prove (1) the standard of care in the locality where the treatment occurred, (2) that the defendant breached that standard of care, and (3) that the breach of the standard was the proximate cause of the injury." Zak v. Brookhaven Memorial Hosp. Medical Center, 54 AD3d 852, 852-853 (2d Dept 2008).

If the movant makes a prima facie showing, then the burden shifts to the party opposing the motion "to produce evidentiary proof in admissible form sufficient to establish the existence of material issues of fact which require a trial of the action." Alvarez v. Prospect Hosp., 68 N.Y.2d 320, 324 (1986) (citation omitted). If "the expert's ultimate assertions are speculative or unsupported by any evidentiary foundation, however, the opinion should be given no probative force and is insufficient to withstand summary judgment." Diaz v. N.Y. Downtown Hosp., 99 N.Y.2d 542 (2002). At the same time, it is well settled that when competing experts present adequately supported but differing opinions as the propriety of the medical care, summary judgment is not properly granted. See Florio v. Kosimar, 79 Ad3d 625 (1st Dept 2010).

As a preliminary matter, contrary to plaintiff's argument, that the FDA black box warning, and the ASO guidelines as to testing patients for Hepatitis B, who are being treated

with highly immunosuppressive therapies like Rituxan, are not determinative of the standard of care. See Toth v Community Hospital at Glen Cove, 22 NY2d 255, 262 (1968) (the standard of care for physicians is one established by the medical profession); See also, 104 AD3d 502,504 (1st Dept 2013) (holding that guidelines at issue were "simply recommendations regarding treatment, and thus, compliance with the guidelines did not, in and of itself, constitute good and accepted medical practice" Instead, in general, "the standard of care for a physician is one established by the profession itself [so that] a physician will usually be insulated from tort liability where there is evidence that he or she conformed to accepted community standards of practice." Spensieri v. Lasky, 94 NY2d 231, 237 (1999).

In this connection, the court notes that the FDA Safety Communication regarding the Black Box warning "recommends (but does not require) that "health care professionals screen all patients for [Hepatitis B] infection before starting treatment with . . . Rituxan." (Plaintiff's Motion, Exh. 7). As for the ASO Guidelines, they state that "[p]hysicians may consider screening patients...of highly immunosuppressive therapy is planned ...[such as] regimes including [Rituxan]." (Id, Exh. 5).

That said, however, based on the affidavits of plaintiff's experts and the evidence in the record, plaintiff has met her prima facie burden of demonstrating that defendant departed from the standard of care by failing to test plaintiff for Hepatitis B before, and during the period, that she was being treated with Rituxan as supported by the ASCO guidelines and the FDA black box warnings requiring such testing. As for causation, these opinions are sufficient to meet plaintiff's burden of showing that the failure to test plaintiff for Hepatitis B resulted in her injuries.

Accordingly, the burden shifts to defendant to controvert plaintiff's showing. Here, defendant has met this burden based on his expert's opinion that defendants' failure to test plaintiff for Hepatitis B was not a departure from accepted medical practice under the circumstances here, including the purported absence of known risk factors for Hepatitis B in plaintiff. Furthermore, while defendant's expert does not specifically address defendant's decision not to test plaintiff for Hepatitis B after she showed signs abnormal liver function, his opinion that it was a reasonable exercise of clinical judgment by Dr. Decter not to screen Ms. David for Hepatitis B both at the start, and throughout her treatment is sufficient to raise an issue of fact in this regard. See Florio v. Kosimar, 79 AD3d at 626 (conflicting expert affidavits raise issues of fact warranting the denial of summary judgment).

Moreover, to the extent plaintiff argues that defendant's expert is not qualified to offer an expert opinion as to whether Dr. Decter departed from standard of care in his treatment of plaintiff, such argument is unavailing. For an expert's opinion to be probative, the expert must possess sufficient training, education and knowledge so that it can be inferred the information provided by the expert is reliable and, once an expert establishes that he or she "possesses the requisite knowledge necessary to make a determination of the issues presented...the issue of an expert's qualification must be left to trial." Limmer v. Rosenfeld, 92 AD3d 609, 609 (1st Dept 2012); Joswick by Joswick v Lenox Hill Hosp , 161 AD2d 352 (1st Dept 1990)(a physician need not be a specialist in a particularly field to qualify as an expert as long as the physician possession the requisite knowledge and the weight of the expert's opinion should be resolved at trial); compare, Ozugowski v City of New York, 90 AD3d 875 (2d Dept 2011) (physician who was internist and cardiologist failed to establish foundation for his opinion regarding psychiatric treatment). Here, defendant's expert has adequately established that he possesses the requisite

knowledge to provide a probative opinion on the issue of whether Dr. Decter committed malpractice in failing to test plaintiff for Hepatitis B before and during her treatment with Rituxan based on his statement that he is "familiar with the applicable standards of care in the treatment and diagnosis of ...[NHL] and Hepatitis B.[4]"

Conclusion

Accordingly, it is

ORDERED that plaintiff's motion for summary judgment is denied; and it is further

ORDERED that the parties shall appear on September 27, 2018 at 10:30 am, in Part 11, room 351, 60 Centre street, New York, NY, for a previously scheduled pre-trial conference.

Dated September 19, 2018

J.S.C.

HON. JOAN A. MADDEN
J.S.C.

[4]The court need not reach defendant's argument regarding the error in judgment rule "which applies to a narrow category of medical malpractice cases in which there is evidence that defendant physician considered and chose among several medically acceptable treatment alternatives." Lacqua v Silich, 141 AD3d 690, 691-692 (2d Dept 2016)(internal citations and quotations omitted).